FEB 2 8 2014

A. 510(k) Summary

This summary of special 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Date Prepared: February 5, 2014

510(k) number: K133702

Applicant Information:
Sontina Medical, LLC
111 Sutro Heights Ave
San Francisco, CA 94121

Contact Person: Robert Peliks
Phone Number: (415) 873 – 3831
Fax Number: (415) 668 – 4884

Device Information:

Classification:	Class II
Trade Name:	Presto Breast Biopsy Device
Common Name:	Biopsy Instrument
Classification Name:	Biopsy Instrument (21 CFR 876.1075)
Product Code:	KNW

Predicate Device Information:
The subject device is substantially equivalent in intended use and/or method of operation to the devices listed in **Table A.1**.

Table A.1 Predicate Device Information

Device Name	Manufacturer	510(k) #
Presto Breast Biopsy Device	Sontina Medical (San Francisco, CA	K120440
Rubicor Magic Breast Biopsy Device	Encapsule Medical (San Francisco, CA)	K071048
Mammotome Hand Held 8 Gauge Probe	Devicor Medical (Cincinnati, OH)	K003297

Device Description:
The Presto Breast Biopsy Device is a sterile, single-use percutaneous biopsy device. The working end of the device includes a stainless steel coring cannula with a razor edge and a stationary coil located within the coring cannula. The handle of the device contains an actuation button, a partoff button, a sample collection chamber, a drive mechanism for rotating the coring cannula and a DC power jack for a 12V input. A reusable, medical grade AC/DC power supply provides 12V to the disposable device. Depressing the button on the handle rotates the coring cannula – allowing the operator to core and transport tissue samples to the collection chamber. The device is used with a coaxial introducer. Actuating the partoff button mechanically adjusts the distal end of the coring cannula between a coring & partoff configuration.

Intended Use:

The Presto Breast Biopsy Device is intended for diagnostic sampling of breast tissue during breast biopsy procedures. It is to be used for diagnostic purposes only and is not intended for therapeutic uses.

The Presto Breast Biopsy Device is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Device Comparison:

The Presto Breast Biopsy device shares many similarities with the predicate devices (K120440, K071048 and K003297). Table A.2 below provides a comparison of the modified device and the predicate devices (K120440, K071048 and K003297). Please note that categories which are equivalent to another 510(k) are denoted as "Same", followed by the 510(k) # in parentheses; categories which are very similar to another 510(k) are denoted "Similar", followed by the 510(k) # in parentheses.

Table A.2 Predicate Device Comparison Table

	K120440 (Sontina)	**K071048 (Rubicor)**	**K003297 (Mammotome)**	**Modified Device (K133702)**
510(k) #	K120440	K071048	K003297	K133702
Product Code	KNW	KNW	KNW	Same (K120440, K071048, K003297)
Guidance Method	Ultrasound	Ultrasound	Ultrasound	Same (K120440, K071048, K003297)
Shaft Diameter	12 Gauge	10 Gauge	8 Gauge	Same (K120440, K071048, K003297)
Method of Device Insertion	Working end of device introduced through coaxial introducer	Working end of device introduced without coaxial introducer.	Working end of device introduced without coaxial introducer.	Same (K120440)
Method of Tissue Dissection	Rotating, forward-advanced round cutter w/ specimen transport element.	Rotating, forward-advancing round cutter w/ specimen severing/transport elements	Rotating, forward-advancing round cutter engages w/ sample notch in trocar	Same (K071048) Similar (K120440, K003297)
Optimal Sample length	Operator control; about 2cm	2cm	2cm	Same (K120440, K071048, K003297)
Method of Tissue Collection/ Transport	Screw-like interaction between stationary coil & spinning outer round cutter	Interaction between inner tubes and spinning outer round cutter.	Interaction between inner features and round cutter.	Same (K120440) Similar (K071048, K003297)

	K120440 (Sontina)	K071048 (Rubicor)	K003297 (Mammotome)	Modified Device (K133702)
Patient Contacting Materials	Stainless Steel tube & Stainless Steel coil (with lubricious coating)	Stainless Steel	Stainless Steel	Same (K120440) Similar (K071048, K003297)
Power Source	DC motor, medical grade 12V AC-DC power supply	DC motor, medical grade 12V AC-DC power supply	Pneumatic & AC-DC power supply	Same (K120440, K071048)
Hand-held procedure	Yes	Yes	Yes	Same (K120440, K071048, K003297)
Disposable Device	Yes (reusable AC/DC adapter)	Yes (reusable AC/DC adapter)	Yes (reusable holster)	Same (K120440, K071048) Similar (K003297)
Target Population	Adults with suspicious soft-tissue lesion(s)	Adults with suspicious soft-tissue lesion(s)	Adults with suspicious soft-tissue lesion(s)	Same (K120440, K071048, K003297)
Anatomical Site	Breast Tissue	Breast Tissue	Breast Tissue	Same (K120440, K071048, K003297)
Location Used	Physician's office or OR	Physician's office or OR	Physician's office or OR	Same (K120440, K071048, K003297)
Biocompatibility	ISO 10993	ISO 10993	ISO 10993	Same (K120440, K071048, K003297)
Device Sterility	EO sterilization	ETO sterilization	ETO sterilization	Same (K120440, K071048, K003297)
Electrical Safety	IEC 60601-1	IEC 60601-1	IEC 60601-1	Same (K120440, K071048, K003297)
Prescription vs. O.T.C.	Prescription	Prescription	Prescription	Same (K120440, K071048, K003297)
Compatibility w/ other devices	Coaxial Introducer	None	None	Same (K120440)
Indications for Use	The Presto Breast Biopsy Device is intended for diagnostic sampling of breast tissue during breast biopsy procedures. It is to be used for diagnostic purposes only and is not intended for therapeutic uses. The Presto Breast Biopsy Device is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide	The Rubicor Magic™ Breast Biopsy Device is intended for diagnostic sampling of breast tissue during breast biopsy procedures. It is to be used for diagnostic purposes only and is not intended for therapeutic uses. The Rubicor Magic™ Breast Biopsy Device is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for	The Mammotome® Biopsy System is indicated to provide tissue samples for diagnostic sampling of breast abnormalities. The Mammotome® Biopsy System is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. The Mammotome® Biopsy System is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality. The extent of a histologic abnormality cannot always	Same (K120440, K071048, K003297)

	K120440 (Sontina)	K071048 (Rubicor)	K003297 (Mammotome)	Modified Device (K133702)
	breast tissue for histologic examination with partial or complete removal of the imaged abnormality. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.	histologic examination with partial or complete removal of the imaged abnormality. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.	be readily determined from palpation or imaged appearance. Therefore, the extent of removal of the palpated or imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures. In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g., fibroadenoma, fibrocystic lesion), the Mammotome® Biopsy System may also be used to partially remove such palpable lesions. Whenever breast tissue is removed, histological evaluation of the tissue is the standard of care. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.	

Non-Clinical Performance Data:
The Presto Breast Biopsy Device was evaluated in the following non-clinical studies: ex-vivo device performance, tensile strength & fatigue, biocompatibility and simulated use testing.

These tests are summarized in **Table A.3**, below.

Table A.3 Summary of Non-Clinical Performance Data

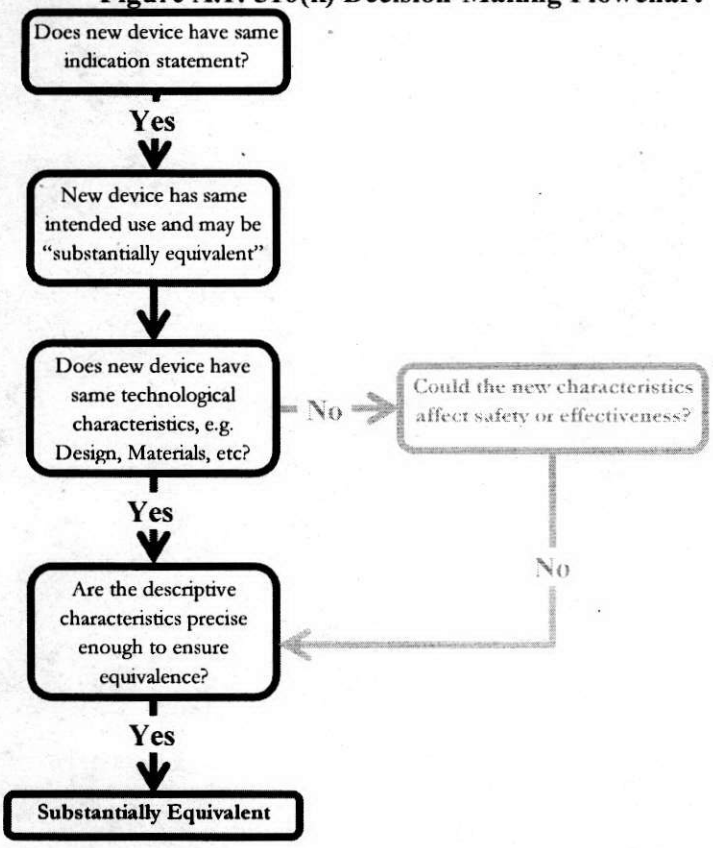
Test ID	Risk	Test Method	Acceptance Criteria	Results
1	Cannula buckles during use	Compression testing	Tube must withstand >15lbf	Pass
2	Tissue not cored/transported	Simulated Use	Mass of 5 samples > 0.13g	Pass
3	Weld breaks	Weld force testing	Weld must withstand >15lbf	Pass
4	Partoff tab breaks	Cycling in & out of tissue	Tab must last >30 cycles	Pass
5	Cytoxicity (biocompatility)	Per ISO 10993-5:2009	None of the cell cultures exposed to the test sample shall show greater than mild reactivity defined as: ≤ 50% of cells round, devoid of intracytoplasmic granules; no extensive cell lysis; and ≤ 50% growth inhibition present. Positive and negative control samples must demonstrate test system suitability	Pass (discrete granules, no lysis, no reduction of growth)
6	Sensitization (biocompatility)	Per ISO 10993-10:2010	The material will be considered acceptable if it has an overall grade of "0" (no visible change) or "1" (discrete or patchy erythema). The reagent blank must show no sensitization reaction.	Pass (grade "0", no sensitization reaction)
7	Irritation or Intracutaneous reactivity (biocompatility)	Per ISO 10993-10:2010	The sample will be considered a non-irritant if the difference between the test extracts and the corresponding control mean score is 1.0 or less.	Pass (overall mean difference (test article – reagent control) was 0.0 for all extracts)
8	Systemic Toxicity (biocompatility)	Per ISO 10993-11:2006	The sample will be considered non-toxic if all of the following conditions are met: a) none of the test extract animals exhibit a significantly greater reaction than the corresponding control animals; b) no more than one animal dies; c) no more than 1 animal displays abnormal behavior such as convulsions or prostration, and c) no more than 2 animals display a body weight loss > 2 grams.	Pass (no mortality, morbidity or weight loss observed)
9	Hemocompatibility (biocompatility)	Per ISO 10993-4:2002	The test article shall have a hemolytic index below 2% (nonhemolytic). Positive and negative control samples must demonstrate test system suitability (the negative control must have a blank corrected % hemolysis value < 2%	Pass (hemolytic index of 0.1% in direct blood

			and the positive control must have a blank corrected % hemolysis value ≥ 5%).	contact, 0.0% as extract)
10	Pyrogenicity (biocompatility)	Per ISO 10993-11:2006	The material is considered non-pyrogenic if each of the three animals does not experience a temperature rise ≥ 0.5°C above its baseline temperature following injection of the test extract. The material is considered pyrogenic if the total maximum temperature rise for all three animals exceeds 3.3°C.	Pass (non-pyrogenic, temp rises were 0.3°C, 0.1°C & 0.0°C)
11	Device stalls during use	Simulated Use w/ side load	Device must cycle w/ 0.8lbf side load	Pass
12	Device becomes nonfunctional	Simulated use	Device must cycle >30 times	Pass
13	Introducer does not engage w/ device	Simulated Use	Device must operate with introducer attached	Pass
14	Partoff tab actuated prematurely	Simulated Use	Mass of 5 samples > 0.13g	Pass

Results of the testing demonstrate that the materials, manufacturing process and design of the Presto Breast Biopsy Device meet the established specifications necessary for consistent performance during its intended use.

Substantial Equivalence:
The changes made & non-clinical performance data support substantial equivalence for the following reasons.

Figure A.1: 510(k) Decision-Making Flowchart



The flowchart above (**figure A.1**) illustrates how the modified device follows the 510(k) "Substantial Equivalence" Decision-Making Process Decision Making Process. The pathway in blue/gray illustrates how the modified device is substantially equivalent to the predicate devices (K120440, K071048 and K003297).
Note: test IDs used below, refer to Table A.3.

- The indication for use is identical.
- The modified device cores the tissue in the same way as K120440 & K071048: depressing a button spins a DC motor, which in turn spins a forward-cutting cannula to core a section of tissue. In all devices (K120440, K071048, K003297 and modified device), once the tissue samples are cored and contained within the cannula, the tissue samples may be transported proximally into a collection chamber, allowing the operator to obtain additional samples without removing the tool from the tissue. The partoff mechanism of the modified device is substantially equivalent to the partoff mechanism of K071048. The PTFE coating of the modified device is substantially equivalent to the coating of K120440. The size range of the modified device is covered by the range of predicate devices (K120440, K071048 and K003297).
    - Alternate pathway (gray), including support from non-clinical performance data: The modified device includes three potential design changes: i) an additional mechanism to aid in severing the tissue sample once it has been cored (no impact to safety/effectiveness, per test IDs 1-4 and 11-14, S.E. to K071048); ii) an alternative PTFE coating for the coil (no impact to safety/effectiveness, per test IDs 2 & 5-10, S.E. to K120440); and iii) a range of different

size cutting cannulas (8 – 12 gauge) (no impact to safety/effectiveness, per test IDs 1-4 & 11-15, S.E. to K120440/K071048/K003297).

- The descriptive characteristics of the modified device are precise enough to ensure equivalence to the predicate devices (K120440, K071048 and K003297).

Conclusion:
Based on the intended use, product, and performance information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed and unmodified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 28, 2014

Sontina Medical, LLC
Mr. Robert Peliks
President
111 Sutro Heights Avenue
San Francisco, California 94121

Re: K133702
Trade/Device Name: Presto Breast Biopsy Device
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: February 5, 2014
Received: February 6, 2014

Dear Mr. Peliks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133702

Device Name
Presto Breast Biopsy Device

Indications for Use *(Describe)*
The Presto Breast Biopsy Device is intended for diagnostic sampling of breast tissue during breast biopsy procedures. It is to be used for diagnostic purposes only and is not intended for therapeutic uses.

The Presto Breast Biopsy Device is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel Date: 2014.02.28 14:58:59 -05'00'

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